



# The Peanut Butter Debate

**A new type of ready-to-use food is changing the way severe malnutrition is treated. But questions remain about how far to push its introduction—and science has a hard time providing the answer**

**SAE SABOUA, NIGER**—On a scorching hot day in this dusty, dry corner of the Sahel, mothers carrying babies and small children line up outside a couple of big tents. Some of the infants look healthy but others are shockingly thin, their arms like broomsticks. They're waiting to enter a "therapeutic feeding center" operated by the French section of Médecins Sans Frontières (MSF). Once inside, the children are measured and weighed and receive a quick health checkup. If they're found to be severely malnourished, they immediately receive a silvery sachet containing a new type of food that might just save their lives.

Open and squeeze the sachet and out pour 92 grams of a brown paste that looks like dark peanut butter. It's called Plumpy'nut, and one serving has 500 calories and plenty of proteins, vitamins, and minerals. Aid organizations like MSF say the paste, a so-called ready-to-use therapeutic food (RUTF), has revolutionized

care for malnourished children. Plumpy'nut has a long shelf life, it does not need to be mixed with water—a major risk with standard treatments based on milk powder—and it is simple for mothers to give to their children at home. Perhaps best of all, children love the sweet, sticky stuff.

But the nutrition world is divided on just how far the introduction of these products should go. MSF wants to move beyond treating severe malnutrition and introduce peanut butter-like pastes to *prevent* that condition, which occurs in some 20 million children in Africa and South Asia every year. In one district in Niger, MSF has started giving the product to as many as 80,000 children between 6 and 36 months, in what's called "blanket distribution." MSF likens the move to the large-scale introduction of antiretroviral drugs in Africa, which it helped pioneer.

But others ask: Where's the science to sup-

port such a plan? Few dispute the power of RUTFs in treating severely wasted children. But there's little evidence that such products work equally well in preventing malnutrition. And besides, skeptics say, adding them to the regular diet of millions of children is too complicated and too costly—MSF's program cost more than \$55 per child in 2007—to keep up in the long run. "For prevention, we need other products," says André Briend, a nutrition expert at the World Health Organization (WHO) in Geneva, Switzerland, who helped invent Plumpy'nut while working as a French government researcher.

The issue has pitted those who want to see solid evidence before embarking on a major aid program against those—impatient with talk about *P*-values, cost-effectiveness, and sustainability—who want to act now. "Thousands of kids are dying," says Milton Tectonidis, a former MSF nutrition expert and a vocal advocate of a massive introduction of RUTFs. "We have enough data now. Do something!"

## A new approach

Part Sahara, part Sahel, Niger is one of the poorest countries in the world. More than 70% of the population is illiterate. Malnutrition is

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this article.

**Sweet fix.** Malnourished children receive sachets of Plumpy'nut at an MSF feeding center in Maradi province, Niger.

pervasive, especially during the so-called hunger gap—the 5 or 6 months before the annual harvest, when the previous year's supplies of sorghum and millet are running out. Protracted dry spells periodically lead to severe food crises, but even in good years, the essentially vegan diet doesn't always provide enough nutrition for fast-growing children younger than 3, says Susan Shepherd, a medical adviser at MSF in Geneva.

Until a few years ago, the standard treatment for severe malnutrition was F100, a milk powder fortified with dozens of vitamins and minerals. F100 was developed in the 1980s by veteran nutrition scientist Michael Golden, now a professor emeritus at the University of Aberdeen, U.K. It needs to be reconstituted with clean drinking water and consumed almost immediately. Left unrefrigerated for a few hours, it turns into a bacterial soup that can cause infectious diseases. That's why F100 is administered only in special nutrition "hospitals" where children often stay as long as 4 weeks with a caretaker, usually their mother.

Those are serious drawbacks. A mother who leaves home and work may put other children or the harvest at risk. Hospital capacities are limited, forcing governments and aid organizations to turn away patients. During a 2002 famine in Angola, MSF treated 8000 children in in-patient centers, Shepherd says, far short of what was needed. Crowded hospitals also help spread infectious diseases. Studies have shown that only between 25% and 45% of patients make a full recovery—and as many as one in five dies.

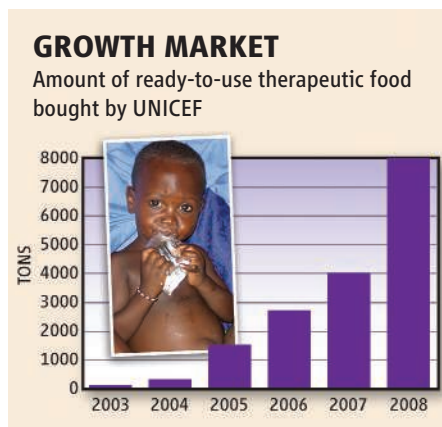
Golden and others started looking for alternatives to F100 in the 1990s. In 1997, Briend, then at the Institute of Research for Development in Paris, teamed up with Michel Lescanne, the director of Nutriset, a food company in Normandy. Lescanne had experimented with Mars-like bars that had almost the same composition as F100; the problem was that they melted easily. Briend found his inspiration in a jar of Nutella, a hazelnut spread that his children loved; the duo developed a paste consisting of roasted, ground peanuts combined with vegetable oil, milk powder, sugar, and a mix of minerals and vitamins.

Plumpy'nut, as they called it, is less than 2% water, which makes it a hostile environment for microbes. Suspended in a fatty environment, the vitamins and minerals are very stable. Plumpy'nut can last for up to 2 years without refrigeration and does not spoil even after the package is opened.

Mark Manary, a nutrition scientist at

Washington University in St. Louis, Missouri, was the first to test the product in clinical trials, in Malawi. Two studies published in 2004 showed that it was "really a breath of fresh air," Manary says: Almost 80% of severely malnourished children recovered. And the home-based treatment regimen proved easy to organize on a large scale.

Experiences elsewhere were similar. Steve Collins, who leads an Irish relief organization called Valid International, saw high recovery rates in Ethiopia, Malawi, and Sudan. MSF was sold on Plumpy'nut after it was able to treat as many as 60,000 children during a severe food crisis in Niger in 2005, says Shepherd—a vast improvement from the Angolan experience. In June of 2007, four United Nations agencies, including WHO and UNICEF, issued a joint statement advocating home treatment with RUTFs for severely malnourished children who don't have other illnesses.



As a result, demand and production have exploded. Nutriset is the biggest producer by far, making more than 15,000 tons in 2008. Although some are dismayed by Nutriset's patents on Plumpy'nut (see sidebar, p. 38), other companies are entering the market as well. In Malawi, Manary set up a Nutriset franchise that churns out 500 tons of Plumpy'nut a year. UNICEF, the biggest RUTF buyer in the world, may purchase as many as 8000 tons in 2008 and expects global production to grow to at least 50,000 tons by 2011.

Given that success, many were surprised when a series of major papers on malnutrition published in *The Lancet* earlier this year offered only lukewarm support for RUTFs. In a vociferous statement, MSF accused the authors of "undermining the support for this lifesaving intervention," which led to a rift with the journal (*Science*, 1 February, p. 555). WHO's Briend was dismayed as well. But the authors of the series have since said that they were misunderstood and that they do in fact support the use of RUTFs to treat severe malnutrition.

## Daunting studies

Although there's consensus about treatment, prevention is a very different matter. MSF and some other nongovernmental organizations are now proposing giving peanut paste as a supplement to children who are moderately malnourished or just at risk of severe malnutrition. Every case of severe malnutrition starts as a milder one, says Shepherd—so why wait until a child is emaciated? "After 2005 we said, 'Hell, let's try to expand it.'"

Many alternatives haven't worked, experts agree. Severe malnutrition is the result of a downward spiral of poor-quality food, weak immunity, infections and diarrhea, loss of energy and appetite, and so on. Many approaches have been tried to stop that cycle: Children have been given an inexpensive, fortified blend of corn and soy flour, or tablets with specific micronutrients such as vitamin A or zinc. Mothers have been taught to breastfeed longer, cook better meals, or wash their hands to avoid infections. But nothing has really proven adequate.

Whether peanut pastes will do better is far from certain. When MSF's program started, only two studies had looked at their ability to prevent severe malnutrition, both by Manary's team in Malawi. They found that moderately malnourished children given RUTFs gained weight faster than those who received corn-soy flour, "but it wasn't a knockout," Manary says.

MSF was not deterred: The fact that it worked so well as a therapy was reason enough to believe it would work in prevention, too, says Shepherd. In 2006, MSF gave Plumpy'nut to all moderately malnourished children in its centers in one district, Guidan Roundji. But simply identifying those children and supplying them with the peanut butter proved a huge logistical challenge; so in 2007, the agency decided to switch to mass distribution to all children between 6 and 36 months of age. Instead of Plumpy'nut, it used Plumpy'doz, a Nutriset product that comes in big jars. Mothers are supposed to give their children just three spoonfuls of Plumpy'doz per day; that way, children get only a quarter of the calories, but their intake of micronutrients stays about the same.

Nutrition science is difficult enough in Western countries; clinical trials to evaluate a food program in a country like Niger are an even bigger challenge, says Rebecca Freeman-Graiss, a researcher at Epicentre, MSF's epidemiology division. The study population is hard to reach, and communication is difficult. Randomizing children to two different regimes within a village would have met with resistance, she says, so the



## PATENTS: A RECIPE FOR PROBLEMS?

**NIAMEY, NIGER**—A giant peanut roaster and grinder, a mixing and filling machine—it doesn't take all that much to produce the new ready-to-use therapeutic foods (RUTFs). A factory barely larger than a house in the quiet outskirts of Niger's capital produces some 500 tons of Plumpy'nut annually. But it can't do so on its own: The company, STA, is a franchise of Nutriset, a company in France that together with the French government owns the patent to Plumpy'nut and similar pastes.

As the market for RUTFs is booming, that situation has come under scrutiny. Aid organizations say there should be no patents on key humanitarian nutrition products, and some worry that Nutriset, a small family-run business, won't be able to meet the soaring demand. "That is absolutely becoming a problem," says Ellen 't Hoen of the Access to Medicine Campaign at Médecins Sans Frontières (MSF), one of Nutriset's main clients.

Most past inventions in humanitarian nutrition, such as a widely used for-

◀ **Homemade.** STA, in the Nigerien capital Niamey, is one of four Nutriset franchises that produce Plumpy'nut in the developing world.

tified milk powder called F100, weren't patented; nor was oral rehydration therapy, a lifesaver for diarrhea patients. But Nutriset and the French Institute of Research for Development obtained patents for Plumpy'nut that last until 2018 and are valid in Europe, North America, and about 30 African countries. Nutriset has threatened lawsuits to keep others—including Compact in Norway and MSI in Germany—from selling similar pastes.

Nutriset's Adeline Lescanne says the company is rapidly boosting its own production capacity and at the same time taking the technology to the developing world, where it helps to stimulate the local economy. It has set up four franchises—in Niger, Malawi, Ethiopia, and the Dominican Republic—that have received equipment and training and now produce Plumpy'nut on a small scale. It has also signed a licensing deal that lets Valid International, an Irish charity, produce its own product under a different name.

MSF and UNICEF, another big buyer, acknowledge that so far there have been no shortages nor evidence of price gouging. Nor is the patent valid in many malnutrition hot spots, including India, where Compact is building a factory and several other companies are interested as well. Still, MSF and UNICEF don't like to be dependent on one major producer for delivering what is becoming an essential product to a large chunk of Africa. MSF says Nutriset and other companies entering the RUTF market should forgo patents—or at least be generous in cutting licensing deals.

It's unclear, meanwhile, whether the patent would withstand a challenge by a competitor. It covers not just Plumpy'nut but also, 't Hoen says, "pretty much any nut paste with milk powder, oil, and micronutrients." Other companies could market a similar product and see what happens in court if sued, she says—but neither Compact nor MSI have been willing to take that risk. Michael Golden, who formulated F100, believes the pressure should not be on Nutriset but on the French government; he hopes that France's foreign minister, Bernard Kouchner, a physician who helped found MSF in 1971, will intervene. —M.E.

researchers compared entire villages to which Plumpy'nut was given with others to which it was not—but of course, no two villages are exactly the same. MSF's decision to move to blanket distribution of Plumpy'doz interrupted the trial, which was supposed to last for 18 months, and forced the researchers to choose a different design that compared the two products. Other aid organizations distributed food in the area as well, introducing more possible confounders.

The data, which are now under review at *The Journal of the American Medical Association*, show that Plumpy'nut does lead to a substantial decrease in the incidence of severe malnutrition, says Philippe Guérin, Epicentre's medical director. But Plumpy'doz—although designed with prevention in mind—appears to be much less effective. That may be because children get fewer calories, but there may be other factors, says Guérin. A survey suggested that rather than giving a little bit every day, some mothers let their children eat it all early on. Plumpy'doz may also be more likely to be shared between the children in a household

than the single-dose Plumpy'nut packages.

Epicentre's conclusion was not welcome news to MSF. MSF's Shepherd says it's important that the researchers analyze their data independently—but says she does not agree with Epicentre's analysis. Tectonidis, who believes Plumpy'doz works in prevention and has no faith in the Epicentre study, went further: In September 2007, while working at the MSF office in Rome, he visited the project in Niger and obtained a copy of the study's database. He then asked Golden, who was not previously involved in the study, to analyze it. Golden's unpublished manuscript says the Plumpy'doz intervention had a "dramatic effect." Guérin says he has not seen Golden's paper and declined to comment on it.

### Is it practical?

Nutrition science aside, there are other questions. Even if Plumpy'nut or similar products work well for prevention, with their hefty price tag, are they the most cost-effective way? How long does the intervention go on, who pays for it, and doesn't it make a population dependent on foreign

aid? "When you're going to tell the world what to do about hundreds of millions of children, it also has to work in practice," Manary says.

One solution may be to make peanut butters cheaper—for instance, by replacing all or part of the powdered milk, the most expensive ingredient, with soy. Perhaps that approach should be combined with very good infection control, says Manary. Many other ideas were on the agenda at a closed expert meeting at WHO headquarters this week, which participants said promised to be lively.

But for the moment, the debate is moot in the Guidan Roudmji district. In a spat unrelated to the scientific debate, the government of Niger accused MSF France of violating several rules and suspended all of its activities on 29 July. Negotiations are ongoing, but for now, both the treatment programs for severely malnourished children and the Plumpy'doz distribution to more than 80,000 children have come to an abrupt halt.

—MARTIN ENSERINK